

ATTACHMENT C
Text of Proposed New Regulation for Public Comment
December 13, 2007

R. 61-____. SOUTH CAROLINA TRAUMA CARE SYSTEMS

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SECTION 100. SCOPE

This regulation establishes standards for implementing provisions of Sections 44-61-510 through 44-61-550 of the South Carolina Code of Laws, 1976, as amended, regarding trauma care systems in South Carolina.

SECTION 200. DEFINITIONS.

ACS: American College of Surgeons.

Bypass (diversion): A medical protocol or medical order for the transport of an EMS patient past a normally used EMS receiving facility to a designated medical facility for the purpose of accessing more readily available or appropriate medical care.

Certificate: A printed document issued by the Department to a hospital that authorizes trauma services at designated levels, i.e., I, II, III, as determined by the Department subject to the provisions of this regulation.

Certificate Holder: The individual, corporation, organization, or public entity that has received a certificate to provide trauma care and with whom rests the ultimate responsibility for compliance with this regulation.

CRNA: Certified Registered Nurse Anesthetist.

Department: The South Carolina Department of Health and Environmental Control (DHEC).

Designation: The formal determination by the Department that a hospital or health care facility is capable of providing a specified level of trauma care services.

Diversion (see “bypass”)

Emergency Department: The area of a licensed general acute care hospital that customarily receives patients in need of emergency medical evaluation and/or care.

EMS: Emergency Medical Services – the arrangement of personnel, facilities, and equipment for the effective and coordinated delivery of emergency care required to prevent and manage incidents that occur from a medical emergency or from an accident, natural disaster, or similar situation.

Emergency Medical Services Advisory Council: Emergency Medical Services council created in pursuant to S.C. Code of Law Section 44-61-30(c) (2002 and Supp. 2006).

Facility: A trauma center having a certificate of designation by the Department.

Field Triage: Classification of patients according to medical need at the scene of an injury or onset of an illness.

Injury: The result of an act that damages, harms, or hurts; unintentional or intentional damage to the body resulting from acute exposure to thermal, mechanical, electrical or chemical energy or from the absence of such essentials as heat or oxygen.

Injury Prevention: Efforts to forestall or prevent incidents that might result in injuries.

Level I: Hospitals that have met the requirements for Level I as stated in Section 303 of this regulation and are designated by the Department.

Level II: Hospitals that have met the requirements for level II as stated in Section 303 of this regulation and are designated by the Department.

Level III: Hospitals that have met the requirements for level III as stated in Section 303 of this regulation and are designated by the Department.

Licensed Nurse: An individual licensed by the South Carolina Board of Nursing as a registered nurse or licensed practical nurse.

Medical Control: On-line or off-line physician direction over pre-hospital activities to ensure efficient and proficient trauma triage, transportation, and care, as well as ongoing quality management.

Participating providers: Those providers who have been approved by the Department for participation in the trauma system and include, but are not limited to, designated trauma centers, designated rehabilitation facilities, and designated fee-for-service physicians who provide trauma care within a designated facility.

Performance Improvement: A method of evaluating and improving processes of patient care that emphasizes a multidisciplinary approach to problem solving and focuses not on individuals, but systems of patient care that might cause variations in patient outcome.

Physician: An individual currently licensed as such by the South Carolina Board of Medical Examiners.

Performance Improvement Program: The process used by a facility to examine its methods and practices of providing trauma care and services, identify the ways to improve its performance, and take actions that result in higher quality performance of trauma care and services for the facility's patients.

Rehabilitation: Services that seek to return a trauma patient to the fullest physical, psychological, social, vocational, and educational level of functioning of which he or she is capable, consistent with physiological or anatomical impairments and environmental limitations.

Repeat Violation: The recurrence of any violation cited under the same section of the regulation within a thirty-six (36) month period. The time period determinant of repeat violation status is not interrupted by changes.

Residency Program: A residency program of the Trauma Center formally affiliated with the Trauma Center where senior residents can participate in educational rotations.

Revocation of Certificate: An action by the Department to cancel or annul a certificate by recalling, withdrawing, or rescinding its authority to operate.

South Carolina Trauma Plan: An organized plan developed by the Department pursuant to legislative directive that sets out a comprehensive system of prevention and management of major traumatic injuries.

State Medical Director (or “State Medical Control Physician): A South Carolina board-certified physician responsible for providing medical oversight to the EMS and trauma system in South Carolina.

State Trauma Advisory Council (or “TAC”): The state advisory council created in this regulation.

Suspension of Certificate: An action by the Department terminating the certificate holder’s authority to provide trauma care services for a period of time until such time as the Department rescinds that restriction.

TAC: (see “State Trauma Advisory Council”)

Trauma: Major injury or wound to a living person caused by the application of an external force or by violence and requiring immediate medical or surgical intervention to prevent death or permanent disability. For the purposes of this regulation, the definition of “trauma” shall be determined by current national medical standards including, but not limited to, trauma severity scales.

Trauma Care Facility (or “trauma center”): Trauma care facility or trauma center hospital that has been designated by the Department to provide trauma care services at a particular level.

Trauma Care Region: A geographic area of the state formally organized in accordance with standards promulgated by the department and has received designation from the department for purposes of developing an inclusive care system.

Trauma Care System: An organized statewide and regional system of care for the trauma patient, including the Department, emergency medical service providers, hospitals, in-patient rehabilitation providers, and other providers who have agreed to participate in and coordinate with and who have been accepted by the Department in an organized statewide system.

Trauma Center: (see “Trauma Care Facility”)

Trauma Center Designation: The process by which the Department identifies facilities within a Trauma Care Region.

Trauma Patient: An injured patient.

Trauma Program: An administrative unit that includes the trauma service and coordinates other trauma-related activities, including, but not limited to, injury prevention, public education, and CMS activities.

Trauma Program Manager: A designated individual with responsibility for coordination of all activities of the trauma service who works in collaboration with the trauma service director.

Trauma Registry: A statewide database of information collected by the Department including, but not limited to, the incidence, severity, and causes of trauma and the care and outcomes for certain types of injuries.

Trauma Service Director: A physician designated by the institution and medical staff to coordinate trauma care.

Trauma System Fund: The separate fund established pursuant to this regulation for the Department to create and administer the State Trauma System.

Trauma Team: A group of health care professionals organized to provide care to the trauma patient in a coordinated and timely fashion. The composition of a trauma team is delineated by hospital policy.

Triage: The process of sorting injured patients on the basis of the actual or perceived degree of injury and assigning them to the most effective and efficient regional care resources in order to insure optimal care and the best chance of survival.

Verification: The Department's inspection of a participating facility in order to determine whether the facility is capable of providing a designated level of trauma care.

201. References.

The following Non-Departmental standards, publications, or organizations are referenced in this regulation:

A. *Resources for Optimal Care of the Injured Patient, the American College of Surgeons Committee on Trauma;*

B. “*Guidelines for Trauma Care Systems,*” adopted by the American College of Emergency Physicians.

SECTION 300. DESIGNATION PROCESS.

301. General.

The Department shall designate levels of trauma care to a hospital by the issuance of a certificate that shall be posted in a conspicuous location for public view in the hospital.

302. Eligibility for Designation

A. Any South Carolina licensed hospitals with a functioning emergency room may apply for trauma center designation.

B. Only hospitals that have received trauma center designation by the Department are eligible for available trauma care reimbursement funds.

C. Requests for trauma center designation shall be accomplished by letter of intent to the Department and by submission of an application.

D. Within one year of the effective date of this regulation, a trauma center designated prior to the effective date of this regulation, which chooses to remain a designated trauma center, shall comply with the provisions of this regulation as well as submit an application and obtain approval by the Department to maintain its status as a designated trauma center.

303. Levels of trauma centers

The Department shall identify trauma centers by levels of care capability as defined in these regulations. The designations shall be Level I, Level II, and Level III. Such determination shall be made by the Department based upon a hospital's ability to meet regulatory requirements to be determined by a special inspection by the Department following the initial request for designation and as an integral part of subsequent renewal procedures. The designation descriptions are as follows:

A. Level I. A Level I hospital shall be the highest level of capability available. The hospital shall have general surgery capability in-house at all times. Anesthesia capabilities are required to be in-house at all times. This requirement may be met with certified registered nurse anesthetists (CRNA) or anesthesiology chief patients. Orthopedic surgery, neurological surgery, and other surgical and medical specialties shall be immediately available. The hospital trauma center may be attached to medical schools or will have residency programs because of the in-house requirements, since fourth year and senior trauma residents may help meet the requirements of the Level I criteria. The Level I hospital trauma center provides education and outreach programs to other area hospitals and the public and shall also conduct trauma-related research.

B. Level II. A Level II hospital trauma center shall have general, neurological and orthopedic surgery available when the patient arrives. Anesthesiology capabilities shall be in-house at all times. This requirement may be met with CRNAs. Other surgical and medical specialties shall be on call and promptly available. These hospitals shall develop local procedures to require that the surgeons be available in the Emergency Department when the patient arrives.

C. Level III. A Level III hospital trauma center shall have general surgery, anesthesia, and radiology on call and promptly available. The general surgeon shall be on call and promptly available. The general surgeon shall also be on call and promptly available in the Emergency Department as the trauma team leader.

304. Categories of Designation

A. Provisional. The Department may initially designate a trauma center as "provisional" for a term not to exceed one year except as granted by the Department. Provisional trauma centers shall have a written work plan of objectives to rectify deficiencies and to demonstrate progress on the work plan throughout the 12-month time period. At the end of the provisional period the department shall grant full designation, extend the provisional period, or suspend the trauma center for cause.

B. Full Designation. The Department may grant full designation to any hospital in full compliance with these regulations, subject to the review process described, for a period not to exceed five (5) years.

Section 305. Application Process

A. Applicants shall submit to the Department a letter of intent for initial designation as a hospital trauma center. The Department shall develop an application packet for hospitals or healthcare facilities that have submitted a letter of intent in seeking initial designation as a trauma center.

B. Application. In addition to the letter of intent, applicants for a designation shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial designation and periodically thereafter at intervals determined by the Department. The application shall include the applicant's oath assuring that the contents of the application are accurate and true and that the applicant will comply with this regulation. The application shall be authenticated as follows:

1. The application shall be signed by the owner(s) if an individual or partnership.
2. If the applicant is a corporation, the application shall be signed by two of its officers.
3. If the applicant is a governmental unit, the application shall be signed by the head of the governmental unit having jurisdiction.

C. The application shall set forth the full name and address of the facility for which the designation is sought and the name and address of the owner of the facility in the event that his or her address is different from that of the facility.

D. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with this regulation. Corporations or partnerships shall be registered with the South Carolina Office of the Secretary of State. Other required application information may include, but is not limited to:

1. System criteria for the level at which the hospital is applying together with the current status of each criteria standard and category of designation sought;
2. Geographic area proposed to be covered;
3. Written affirmation of compliance with all applicable federal Occupational Safety and Health Association (OSHA) requirements or guidelines;

E. If there is a designated trauma center or centers at the same or higher level of designation in the proposed geographical area to be served by the applicant, the applicant shall include in its application the following:

1. A statement of the proposed role of the applicant hospital assuring that the applicant's trauma program and activities would not have a negative financial or operational impact on the existing designated trauma center (s) program or services; and
2. A statement by the Regional Trauma Advisory Committee that the proposed trauma program of the applicant is consistent with and addresses the needs of the regional trauma program as described in the approved regional trauma plan.

F. The application shall become the property of the Department and shall be considered public information at the end of the designation process, subject to state and federal laws.

306. Designation

A. As soon as practical, but no later than sixty (60) days after receipt of the on-site report inspection document, the State Trauma Advisory Council, or a subcommittee thereof, shall make written recommendations to the Department regarding trauma center designation based on:

1. The Department's evaluation of pre-review documentation submitted as part of the application;
2. The evaluation and recommendations from the Department's on-site review team;
3. The ability of each applicant to comply with goals of the State Trauma Plan.

B. After completion of the on-site review and after consideration of the application by the Trauma Advisory Council, the Department may require the hospital to submit an application for a lower designation, to be followed by an on-site review.

C. With the recommendation of the State Advisory Trauma Council, the Department shall notify the hospital of the level of designation by the Department.

D. The Department shall require the hospital, after receiving notification of the decision, to respond in writing within ten (10) working days to accept or decline the proposed designation.

307. Process of Re-designation

A. Scheduled re-designation inspections of currently designated trauma centers shall occur in an interval of no greater than five (5) years.

B. Designated trauma centers shall be notified by the Department within six (6) months of the trauma center's scheduled date for the submission of the application for re-designation.

C. If a significant change in the designated trauma center's staffing or resource capabilities occurs at any time during the trauma center's designation period, an inspection may be conducted by the Department as needed to assure compliance with the regulatory requirements. If such inspection reveals that the trauma center may not be meeting regulatory requirements, the Department may require that the trauma center undergo a complete trauma center re-designation verification inspection prior to the next scheduled re-designation date.

D. If the Department determines that a complete on-site inspection shall be conducted, the Department shall give the trauma center a minimum of thirty (30) days to prepare. If, prior to the trauma center's scheduled re-designation inspection date, a focused inspection or unscheduled inspection by the Department has been conducted, this review(s) will not change the scheduled re-designation inspection date.

308. Appeals to Decision for Designation or Non-Designation

Any Department decision involving the issuance, denial, renewal, suspension, or revocation of a certificate of designation may be appealed by an affected hospital trauma center with standing pursuant to applicable law, including S.C. Code Ann. Sections 44-1-50 and 44-1-60 (1976, as amended).

309. Change in Trauma Center Designation Status

A. A designated trauma center shall have the right to withdraw as a trauma center or to request a designation lower than their current designation level by giving a ninety (90) day notice to the Department.

B. A designated trauma center shall:

1. Notify the Department within five (5) calendar days if it is unable to comply with any of the criteria standards for its level of designation and its reasons for non-compliance.

2. Notify the Department if it chooses to no longer provide trauma services commensurate with its designation level.

C. If the trauma center chooses to apply for a lower level of designation, the Department, at its discretion, may repeat all or part of the designation process in accordance with this regulation.

310. Notification of Public of Trauma Center Designation Status

A. At the time of designation, or revocation of designation, or of any change in the status of a hospital's designation as a trauma center, the Department shall report such changes to the public by means of public record within thirty (30) days of the change of said hospital's trauma center designation status. The Department shall also notify licensed emergency medical service providers of the change of trauma center designation status.

B. The Department and the members of the on-site inspection team shall maintain confidentiality of information, records, and reports developed pursuant to on-site reviews as permitted by state and federal laws.

SECTION 400. CERTIFICATE OF DESIGNATION REQUIREMENTS.

401. Certification Requirements

A. Certificate. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or market itself or represent itself as a trauma center or use similar terminology, e.g., "trauma hospital", "trauma facility", in South Carolina without first obtaining a certificate of designation from the Department. When it has been determined by the Department that an entity claims, advertises, or represents itself as a trauma center and is not designated by the Department, the entity shall be ordered by the Department to cease operation immediately.

B. Compliance. A certificate of designation shall not be issued to an entity until the owner and/or operator of that entity has demonstrated to the Department that the facility is in substantial compliance with these standards.

1. A copy of the trauma center criteria standards and regulations shall be maintained by the provider to whom the certificate is issued and accessible to all staff members.

2. No provider that has been issued a certificate for a trauma center at a specific address shall relocate or establish a new trauma center without first obtaining authorization from the Department.

3. No trauma center shall, in any manner, advertise or publicly assert that its trauma designation affects the hospital's care for non-trauma patients or that the designation would influence the referral of non-trauma system patients.

C. Issuance and Terms of the Certificate of Designation.

1. A certificate is issued by the Department and shall be displayed in a conspicuous place in a public area in the trauma center.

2. The trauma center shall maintain a business address and telephone number at which the trauma center may be reached during business hours.

3. The issuance of a certificate does not guarantee adequacy of individual care, treatment, procedures, and/or services, personal safety, fire safety or the well-being of any patient.

4. A certificate is not assignable or transferable and is subject to revocation at any time by the Department for the provider's failure to comply with the laws and regulations of this State.

5. A certificate shall be effective for a specific trauma center, at a specific location(s), for a period of five (5) years following the date of issue. A certificate shall remain in effect until the Department notifies the certificate holder of a change in that status.

Section 402. Exceptions to the Standards

The Department has the authority to make exceptions to these standards when it is determined that the health, safety, and well-being of the patients will not be compromised and provided the standard is not specifically required by statute.

SECTION 500. ENFORCING REGULATIONS.

501. General

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed hospital trauma center in order to enforce this regulation. Such areas of review may include, but not be limited to, trauma patient records, trauma process improvement plans, committee minutes, and physical facilities.

502. Inspections and Investigations

A. An on-site inspection shall be conducted prior to initial designation certification of an applicant hospital for Levels I, II, and III trauma centers prior to designation. Subsequent inspections may be conducted as deemed appropriate by the Department.

B. All facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the South Carolina Code of Laws.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records. If photocopies are made for the Department, they shall be used only for purposes of

enforcement of regulations and confidentiality shall be maintained. The physical area of inspections shall be determined by the extent to which there is potential impact or effect upon patients as determined by the inspector.

D. A facility found noncompliant with this regulation shall submit a written plan of correction to the Department, signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe:

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences;
3. The actual or expected completion dates of those actions.

E. Information received by the Department through filed reports, inspections, or as otherwise authorized under this regulation shall not be disclosed publicly in such a manner as to identify hospitals or other participating providers except in proceedings involving the denial, change, or revocation of a trauma center designation or type.

F. The Department and the members of the on-site inspection team shall maintain confidentiality of information, records, and reports developed pursuant to on-site reviews as permitted by state and federal laws.

G. The Department reserves the right to make exceptions to these regulations where it is determined that the health and welfare of those being served would be compromised.

503. Inspection Report for Designation

A. The inspection team shall provide the Department with the written inspection report and the recommendations to the Department of the on-site review. At a minimum, the team's written recommendations shall include a description of the applicant's trauma program strengths, non-critical deficiencies and critical deficiencies.

B. Within thirty (30) days of receipt of the information from the site inspection team, the Department shall forward written findings and recommendations to the State Trauma Advisory Council.

C. The Council, or a subcommittee thereof, shall review the reports and recommendations of the on-site review team, consider any unique attributes or circumstances that make the facility capable of meeting particular or special community needs, and render a recommendation to the Department.

D. The Department shall make the final determination of designation regarding each application upon consideration of all pertinent facts, including the recommendation of the Trauma Advisory Council.

504. Inspection Team Composition

A. There shall be a multi-disciplinary on-site inspection team composed of individuals knowledgeable in trauma care and systems, appropriate to the level of designation requested.

B. For the initial inspection, the team shall include but not be limited to:

1. A trauma surgeon;

2. An emergency physician;
3. A trauma nurse coordinator.

C. The composition of inspection teams subsequent to the initial inspection shall be determined by the Department. Such teams shall consist of professionals who:

1. Do not live or work in the same state or region as the applicant for the designation of Levels I and II trauma centers, and
2. Have been employed in a state- designated or American College of Surgeons-verified trauma center within the past three calendar years; and
3. For teams reviewing applicants for Level III designation, must have attended a Department-sponsored site reviewer training workshop.

D. There shall be no conflict of interest between any inspection team member and the hospital for which the team member has been selected.

E. A hospital applying for a designation may, at its discretion, request a verification site inspection by representatives of the American College of Surgeons, or other national organization where its standards are, at a minimum, equal to the criteria set forth in this regulation. The Department may accept the findings of the verification site visit or may request additional information or additional verification as necessary to ensure that the hospital meets the criteria set forth in this regulation. The Department will incorporate a copy of the findings in the report to the Trauma Advisory Council recommending or not recommending designation at the level for which applied.

505. Protocol for Inspections

The applicant's administration, faculty, medical staff, employees and representatives are prohibited from having any contact with any on-site review team member after the announcement of the team members and before the on-site review, except as authorized by the Department. A violation of this provision may be grounds for denying that applicant's proposal as determined by the Department.

506. Content of Inspection

The on-site review team shall evaluate the appropriateness and capabilities of the applicant to provide trauma care services, and validate the hospital's ability to meet the responsibilities, equipment and performance standards for the level of designation sought and to meet the overall needs of the trauma system in that region.

507. Investigation Procedures

A. Any person or entity may communicate a complaint or knowledge of an incident of any alleged violation of these regulations to the Department. Complaints shall be submitted in signed written form to the Department. The Department may begin an investigation without a signed written complaint if there is sufficient cause.

B. All designated trauma centers are subject to investigation at any time without prior notice by individuals authorized by the Department.

C. At the conclusion of the Department's preliminary investigation, the Department shall report its findings to the trauma center in writing, including any requirements for corrective action.

508. Consultations

The Department shall provide technical assistance and support to the State Trauma Advisory Council, the Medical Control Committee, hospitals or other healthcare facilities, and EMS providers as necessary to carry out the State Trauma Plan.

SECTION 600 - ENFORCEMENT ACTIONS

601. Enforcement Actions

A. When the Department determines that a designated trauma center is in violation of any statutory provision, rule, or regulation relating to the duties therein, the Department may, upon proper notice to that entity, impose a monetary penalty and/or deny, suspend, and/or revoke its certificate of designation.

B. The Department may impose monetary penalties on any licensed emergency medical service provider found noncompliant with this or other related statute or regulations.

602. Violation Classifications

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of any persons or a substantial probability that death or serious physical harm could occur. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time established by the Department may be considered a subsequent violation.

B. Class II violations are those that the Department determines to have a negative impact on the health, safety or well-being of persons in the facility. The citation of a Class II violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time established by the Department may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in this regulation. The citation of a Class III violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time established by the Department may be considered a subsequent violation.

D. In arriving at a decision to take enforcement action, the Department will consider the following factors:

1. The number and classification of violations, including repeat violations;
2. The specific conditions and their impact or potential impact on health, safety or well-being of the patients;

3. The efforts by the facility to correct cited violations;
4. The overall conditions of the facility;
5. The facilities history of compliance; failure or refusal to comply with the provisions of Regulation 61-16.
6. The failure or refusal to comply with the provisions of this regulation;
7. The misrepresentation of a material fact about facility capabilities or other pertinent circumstances in any record or in a matter under investigation for any purposes connected with this chapter;
8. The prevention, interference with, or any attempts to impede the work of a representative of the Department in implementing or enforcing these regulations or the statute;
9. The use of false, fraudulent, or misleading advertising, or any public claims regarding the hospital's ability to care for non-trauma patients based on its trauma center designation status;
10. The misrepresentation of the facility's ability to care for trauma patients based on its designation status;
11. The failure to comply with the requirements of these regulations;
12. The failure to provide data to the Trauma Registry;
13. Any other pertinent conditions that may be applicable to statutes and regulations.

E. Pursuant to S.C. Code Ann. Section 44-61-520 (E) & (F) (1976, as amended) the Department may impose monetary penalties.

MONETARY PENALTY RANGES

| FREQUENCY | CLASS I | CLASS II | CLASS III |
|--------------------------|-------------------|-------------------|-------------------|
| 1 st | \$500 - \$1,500 | \$300 - \$800 | \$100 - \$300 |
| 2 nd | \$1,000 - \$3,000 | \$500 - \$1,500 | \$300 - \$800 |
| 3 rd | \$2,000 - \$5,000 | \$1,000 - \$3,000 | \$500 - \$1,500 |
| 4 th | \$5,000 | \$2,000 - \$5,000 | \$1,000 - \$3,000 |
| 5 th | \$7,500 | \$5,000 | \$2,000 - \$5,000 |
| 6 th and more | \$10,000 | \$7,500 | \$5,000 |

F. Any Department decision involving the issuance, denial, renewal, suspension, or revocation of a certificate and/or the imposition of monetary penalties where an enforcement action order has been issued

may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

SECTION 700. STAFFING

701. General

A. Trauma centers shall have adequate staff to include physicians on-duty twenty-four (24) hours per day.

B. Detailed components of support services and medical, nursing and ancillary staffing for each level shall meet the recommendations outlined in the *Resources for Optimal Care of the Injured Patient by the American College of Surgeons*.

SECTION 800. GENERAL FACILITY, EQUIPMENT AND CARE REQUIREMENTS

801. Physical Facilities

Environment, equipment, supplies, and procedures utilized in the care of trauma patients shall meet the recommendations outlined in the *Resources for Optimal Care of the Injured Patient by the American College of Surgeons*.

802. Trauma Care of the Patient (Transport)

Each hospital providing trauma care services shall establish and implement a written plan that outlines the process, providers, and methods of providing risk-appropriate stabilization and transport of any patient requiring specialized services. This plan shall be updated on an annual basis and shall include, but not be limited to, procedures outlining:

A. Communication between referring hospitals, transport teams and medical control, and providers and families;

B. Indications for both acute phase and return transport between trauma care hospitals, to include essential contact persons and telephone numbers for referral and transport;

C. A list of all medical record copies and additional materials to accompany each patient in transport.

803. Trauma Care Services.

A. Each trauma care facility shall provide emergency services that include life-saving procedures when life is in jeopardy. An appropriate record shall be maintained on each person who presents for emergency services.

B. Equipment and services shall be provided to render emergency resuscitative and life support procedures pending transfer of the critically ill or injured to a hospital trauma center with definitive care capabilities. A minimum capacity shall be established and equipment provided to perform procedures such as hemostasis, therapy of traumatic shock, maintenance of airway and cardiopulmonary resuscitation.

C. Basic services, such as x-ray and routine laboratory services, shall be maintained and staff available for call.

D. A physician shall be available and on call at all times. A registered nurse and ancillary personnel trained in emergency procedures shall be on duty within the hospital and available twenty-four (24) hours a day to assist in providing trauma care services.

E. No person, regardless of his ability to pay or location of residence, may be denied trauma care if a member of the admitting hospital's medical staff or, in the case of a transfer, a member of the accepting hospital's staff determines that the person is in need of trauma care services.

F. If the care required for any patient is not available at the facility, arrangements shall be made for transfer to a more appropriate hospital trauma center. Prior to the transfer of a patient to another location, the receiving hospital trauma center shall be notified of the impending transfer.

SECTION 900. PATIENT RIGHTS.

901. General

The facility shall comply with all relevant federal, state, and local laws and regulations concerning discrimination, e.g., Title VII, Section 601 of the Civil Rights Act of 1964.

902. Grievances and Complaints

A. The facility shall establish a written grievance and complaint procedure and patients shall be informed of this procedure, including the address and phone number of the Department's Division of Emergency Medical Services and Trauma.

B. The facility shall have patients sign a statement of understanding regarding the grievance and complaint procedure prior to patient discharge.

SECTION 1000. STATEWIDE TRAUMA REGISTRY.

1001. Purpose of Trauma Registry.

A. The Department shall establish a trauma data collection and evaluation system, known as the "Trauma Registry." The Trauma Registry shall be designed to include, but not be limited to, trauma studies, patient care and outcomes, compliance with standards of verification, and types and severity of injuries in the State.

B. The Department may collect, as considered necessary and appropriate, data and information regarding patients admitted to a facility through the emergency department, through a trauma center, or directly to a special care unit. Data and information shall be collected in a manner that protects and maintains the confidential nature of patient and staff identifying information

1002. Requirement to Submit Data.

A. Each designated trauma center shall participate in the System Trauma Registry by:

1. Identifying a person to be responsible for coordination of trauma registry activities.

2. Downloading required trauma data as stipulated by the Department.

B. Only patient care records that are included in the hospital's trauma registry may be requested for review by site inspection teams at the time of initial designation or by the Department for focused reviews during any time of the hospital's designation period.

C. Each trauma center designated by the Department shall provide data to the Department at least quarterly (March, June, September, December). The data should be received by the Department no later than thirty (30) days following the end of each quarter. The trauma center shall establish measures to ensure that the data entered in the trauma registry is at least 95% (ninety-five percent) correct. The trauma center shall designate an individual to establish protocols or procedures to ensure that data is properly entered.

1003. Inclusion and Exclusion Criteria.

Patient inclusion and exclusion criteria shall be established by the Department under the guidance of the Trauma Advisory Council and its subcommittees.

1004. Confidentiality Protection of Data and Reports

Records and reports created with the use of the trauma data collection and evaluation system shall be held confidential within the Department and shall not be available to the public, admissible as evidence, or subject to discovery by subpoena. Information that identifies individual patients shall not be disclosed publicly without the patient's consent.

SECTION 1100. HOSPITAL RESOURCES DATA BASE.

1101. Purpose.

A. The Hospital Resources Data Base shall be used to monitor hospital resources on a continuous basis, disseminate information throughout South Carolina's healthcare system, and inform users of the clinical services offered, laboratory capabilities, and bed capacity.

B. The department shall manage the Hospital Resources Data Base for South Carolina participants.

1102. Required Participation.

All trauma centers designated by the department shall utilize the Hospital Resources Data Base. Information shall be updated on a daily basis, which shall include, but not be limited to: hospital bed availability, specialty service capability, and disaster resources.

SECTION 1200. TRAUMA CARE FUND

1201. Eligible Recipients of Fund.

Trauma centers, rehabilitation centers, physicians, Emergency Medical Services providers licensed by the Department, Regional EMS Councils, and the Division of EMS and Trauma are eligible to receive a portion of the Trauma Care Fund appropriated by the South Carolina General Assembly.

1202. Allocation of Fund.

The Department, with the advice of the Trauma Advisory Council and its subcommittees shall determine the priority of disbursements, as well as a disbursement formula based on the following criteria:

A. Funds shall be disbursed equally among the fifteen (15) Emergency Medical Services providers with the highest fatality rates per capita due to motor vehicle collisions. The Department shall utilize statistics provided by the South Carolina Department of Public Safety to determine eligibility.

B. Funds shall be disbursed to the Regional EMS Councils on an equal basis and shall be based on the total appropriation for that year.

C. The criteria for the distribution of hospital, physician, and rehabilitation facility funds shall be established by the Department with the advice of the Trauma Advisory Council and its subcommittees.

SECTION 1300. PERFORMANCE IMPROVEMENT SYSTEM.

1301. General

Performance improvement (PI) programs shall be developed at the state and trauma center levels.

1302. Statewide Trauma System PI Plan

The Department shall develop and maintain a Statewide Trauma System PI Plan with input from the state Trauma Advisory Council and its subcommittees. This plan shall, at a minimum, report:

A. Summary statistics and trends for demographic and related information about trauma care for the state Trauma Advisory Council;

B. Outcome measures for evaluation of clinical care and system-wide quality assurance and performance improvement programs.

1303. Trauma Center PI Plan

The trauma Center PI program shall include regular in-house multi-disciplinary trauma conferences that address:

A. The participation of members of the trauma team,

B. The participation of the person responsible for coordination of trauma registry activities,

C. The participation of the hospital trauma center's designated rehabilitation coordinator as appropriate,

D. The provision of feedback to staff and services areas that are involved with trauma care, and

E. The provision of appropriate reports to the state performance improvement program.

SECTION 1400. ADVISORY COMMITTEES.

1401. Purpose of State Trauma Advisory Council

A. The Trauma Advisory Council shall act as an advisory body for trauma care system development and provide technical support to the department in areas of trauma care system design, trauma standards, data collection and evaluation, performance improvement, trauma system funding, and evaluation of the trauma care system and trauma care programs.

B. The State Trauma Advisory Council, with the concurrence of the State EMS Advisory Council and the Department, shall adopt guidelines for its operations. These guidelines shall include attendance, maintenance of minutes, and other guidelines necessary to assure the orderly conduct of business and shall have the following other functions:

1. Periodically review and comment on the Department's regulations, policies and standards for trauma;
2. Advise the Department regarding trauma system needs and progress throughout the state;
3. Review and comment on regional trauma plans;
4. Periodically review local, regional, or state pre-hospital trauma triage guidelines;
5. Advise the Department on injury prevention and public information/educational programs.

1402. Medical Control Committee

A. The Medical Control Committee is a subcommittee of the Trauma Advisory Council and the EMS Advisory Council composed of medical control physicians from each of the state's four EMS regions, physician members of the EMS and Trauma Advisory Councils, and the State Medical Control Physician.

B. The Medical Control Committee is an advisory board responsible for the establishment of approved pre-hospital equipment and skills, the State EMS Formulary and other issues pertaining to EMS and trauma care.

SECTION 1500. TRAUMA TRIAGE AND TRANSPORT GUIDELINES.

1501. Purpose

The Department, with the advice of the Trauma Advisory Council, shall establish Trauma Triage and Transport Guidelines to improve the quality of trauma care being provided to patients by ensuring that EMS providers transport patients to the appropriate level of trauma care.

1502. Required Participation

All licensed Emergency Medical Services providers shall provide the Department and all trauma centers utilized by the EMS provider with a copy of their system's trauma triage and transport policy that shall be based on the guidelines established by the Department.

SECTION 1600. TRAUMA SYSTEM PLANS.

1601. General

- A. The Department shall establish a state trauma system plan.

B. The Department shall consider the advice and recommendations of any affected regional trauma agency in developing the state trauma system plan. The Department shall use the state trauma system plan as the basis for establishing a statewide inclusive trauma system.

C. In developing the state trauma system plan, the Department shall consider any available federal model trauma plans.

D. The Department shall develop and update the State Trauma System Plan periodically with advice from the Trauma Advisory Council.

1602. Trauma Regions

A. As part of the state trauma system plan, the Department shall establish trauma regions.

B. Regions shall cover all geographical areas of the state and have boundaries that are coterminous with the boundaries of the emergency medical service regional areas. These regions may serve as the basis for the development of Department-approved regional trauma plans. However, the delivery of trauma services by or in coordination with a trauma agency may extend beyond the geographic boundaries of the EMS or Trauma Regions.

C. Trauma Regions are established with the same geographic boundaries as the Emergency Medical Services regions.

1603. Trauma Center Internal Trauma Plan

Each designated trauma center shall develop an internal trauma plan that based on data supplied by the trauma registry and other sources and shall provide for the ongoing assessment and improvement of performances of the trauma center. The plan shall include, but not be limited to:

A. The review of trauma care delivery;

B. The review of all trauma-related deaths;

C. The identification and analysis of injury trends and patient care outcomes;

D. The review of policies regarding confidentiality of data elements related to identification of provider and trauma center care outcomes, in accordance with applicable state and/or federal law;

E. The enforcement of policies regarding confidentiality of records and committee minutes, including a requirement that each attendee of the trauma PI committee meeting be informed in writing of the confidentiality requirement. Information identifying individual patients shall not be publicly disclosed without the patient's consent in accordance with applicable state and federal laws,

F. The implementation of provisions for feedback to the Department and the approved Trauma Advisory Committees on identified trauma issues and concerns.

SECTION 1700. SEVERABILITY.

1701. Severability

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.